

ERS submission to the European Commission's consultation for the proposal on the European Health Emergency Preparedness and Response Authority

Science and public health first

The European Respiratory Society supports the creation of a Health Emergency Preparedness and Response Authority (HERA) with an aim to 'address **all** future serious cross-border threats to health'. The advancement of science and the development of innovative health solutions must be the key drivers of the new authority. We therefore support an ambitious mandate for the authority that could allow HERA to effectively cover the whole value chain from petri dish to patient.

Policy options

Options 2.2 for an operational and infrastructure authority or option 3 for an end-end authority, outlined in the inception impact assessment would allow HERA to properly cover the full array of serious cross-border threats to health. We encourage Member States and the European Parliament to fully support the Commission's proposal for this new authority along these lines and to the maximum extent possible under the Treaty.

Future health threats and challenges

We do not need to be futurologists to predict that future health threats will unfortunately affect the respiratory system and the lungs as SARS-CoV2 and MERS-CoV, (and other acute-lung-injury causing coronaviruses) have done. The pandemics of the last century were caused by influenza viruses resulting in respiratory disease. In the beginning of this century, asthma was identified as the most prevalent underlying host condition associated with hospitalisation in the 2009 flu-pandemic caused by influenza A (H1N1) pdm09 (pH1N1).

Antimicrobial resistance is resulting in a global crisis of Multi Drug Resistant Tuberculosis (MDR-TB) that threatens to reverse the gains made from decades of effort to contain the TB epidemic. Multi drug resistance pathogens are typically respiratory pathogens and most antibiotics prescribed in Europe are for respiratory infections.

The commonest pathogen identified in Chronic Obstructive Pulmonary Disease *Haemophilus influenzae* is becoming resistant as is *Streptococcus pneumoniae* the leading cause of pneumonia in children under 5 years of age.

A major knowable future health threat is climate change and related air pollution. Climate change represents a massive direct threat to respiratory health by promoting or aggravating respiratory diseases or indirectly by increasing exposure to risk factors for respiratory diseases.

It is important that HERA has all these threats fully on its radar. There are certain other threats to health that are currently unknowable, and HERA must have the dexterity and capabilities to roll into action once they become defined.

Cross sectoral – multidisciplinary – no silos

It is particularly important that HERA introduces incentives for investments in unmet public health needs, such as research and the development of scarce medical countermeasures, market failures, novel antimicrobials, and other major health gaps. There must be long term planning and cross sectorial involvement. Health threats are never siloed nor should our structures be. HERA must be fully linked with other initiatives such as the Pharmaceutical Strategy and the reinforced Cross Border Health Threats legislation and with other agencies such as EMA, ECDC but also WHO and BARDA.

Training – role of health care professionals and scientific societies

We advocate that HERA should have strong links to biomedical researchers, academia, and clinicians. Academia and public funded researchers have come up with many of the solutions to the current pandemic and it is right therefore that they should have a strong role in HERA. Moreover, the role of healthcare professionals across respiratory wards and critical care units has been pivotal in this pandemic and this should be taken into account in the design and future programmes of HERA. We welcome the reference to training on biopharmaceutical skills in the impact assessment and we stand ready to assist in capacity building and projects of HERA to prepare our 40,000 membership of respiratory healthcare workers and scientists for future health threats.

Scope – act local, reach global

Perhaps there is a concern around competences, as the inception impact assessment seems unnecessarily restrictive in places. While we welcome the rapid work that has been unveiled recently with the HERA incubator, we maintain that the Commission should strive for a

comprehensive mandate. This would allow HERA to coordinate all counter medical measures. Not just vaccines and therapies but non-medical counter measures should be considered as well - as the current pandemic shows. It is important that the right response is designed to the specific health threat.

The impact assessment is understandably locally focused on the EU. However, HERA must also be able to look outwards and have a global outlook. Given that these threats do not recognise international borders, it seems very clear that HERA must have global reach in order to be effective and to be able to interact proactively with authorities from other countries.

Peacetime preparation and horizon scanning

Finally, horizon scanning, and peacetime preparation is very important as the more knowledge we have of all factors (viral, bacterial, fungal, human, animal, genetic, immunologic, epidemiologic, environmental etc.) that determine global outbreaks the more we might be able to predict and prepare for future pandemics and develop vaccines and other counter measures that prevent and protect against them. Studies in all these areas should be supported as should academic-led independent clinical trials to discover new medicines. As the example of COVID-19 or the example of asthma in pH1N1 shows, it is crucial that the interconnections between emerging health threats and chronic conditions are considered in the activities of the authority.